Intraocular Lens Opacification After Descemet's Membrane Endothelial Keratoplasty—Risk Factors and Outcomes After Intraocular Lens Exchange

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Purpose: To determine risk factors for intraocular lens opacification (IOLop) after Descemet membrane endothelial keratoplasty (DMEK) and to analyze clinical outcomes after IOL exchange.

Methods: *Cross-Sectional Study*: Analysis of all cases of IOL exchange because of post-DMEK IOLop with a minimum of 6-month postoperative follow-up observed in clinic between November 2021 and April 2022. Main outcomes analyzed at the study visit were change in logarithm of the minimum angle of resolution (logMAR) best-corrected visual acuity after IOL exchange, endothelial cell loss (ECL), and graft survival. An historical cohort of 232 pseudophakic DMEK eyes was retrospectively analyzed to determine risk factors for post-DMEK IOLop.

Results: *Cross-Sectional Study*: Four eyes were observed (median follow-up = 45 (35.5–86.8) months). IOL materials were hydrophilic acrylic IOLs in 2 eyes and hydrophobic–hydrophilic in the other 2. At the study visit, improvement in median best-corrected visual acuity after IOL exchange was statistically significant (0.25 (0.19–0.41) logMAR to 0.00 (0–0.10) logMAR; $P = 0.041$). ECL ranged between 57.7% and 85.3%, without cases of graft failure. In the historical cohort, 21 eyes (9.05%) had some IOLop. In multivariate logistic regression model (105 eyes where IOL material data was available), IOLs with high water content material (odds ratio = 65.5, $P = 0.0005$) and rebubbling (odds ratio = 9.51, $P = 0.0138$) were independent risk factors for post-DMEK IOLop.

Conclusions: Post-DMEK IOLop is infrequent, but a non-neglectable proportion of cases may require IOL explantation. IOL exchange is safe and effective in these eyes but may pose a risk for increased ECL. This study confirms that IOL material and number of rebubblings are major risk factors for post-DMEK IOLop.

Key Words: Descemet membrane, endothelial keratoplasty, intraocular lens opacification, risk factors

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Descemet membrane endothelial keratoplasty (DMEK) has become the gold standard technique for the treatment of corneal endothelial disease and failure, with a rapid visual recovery, low risk of allograft rejection, and good medium-term survival rates. The most common complication after DMEK is graft detachment and the need for rebubbling; other postoperative complications (apart from rejection) are less frequent and include increased intraocular pressure (IOP), cystoid macular edema (CME),[1] and intraocular lens (IOL) opacification. Intraocular lens opacification (IOLop) is an infrequent but likely underreported complication after DMEK, with scarce literature data.[2–4] Post-DMEK IOLop is because of the deposition of calcium and phosphate in the IOL surface and/or subsurface.[3,5,6] There are several proposed risk factors for IOLop after endothelial keratoplasty (EK),[7] with IOL materials with high water content (WC) being the most consistently reported risk factor.[3,4]

Intraocular lens opacification can cause significant impact in vision, and in these cases, IOL explantation may be indicated. However, there is limited data available on the incidence of post-DMEK IOLop requiring explantation because of significant impact in visual acuity, and there are no data regarding the long-term visual and graft outcomes after IOL explantation in this setting. The aim of this study was to analyze the long-term visual and graft outcomes after IOL explantation because of post-DMEK IOLop and to determine the risk factors for post-DMEK IOLop.

MATERIALS AND METHODS

The study was conducted according to the tenets of the Declaration of Helsinki and was approved by the local Research Ethics Committee (*COD IMO 211022-197*). All patients signed an institutional review board–approved informed written consent for the study.

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TABLE 1. Cross-Sectional Study Patients' Characteristics Before Explantation of the Opacified Intraocular Lens

Patients	Sex	Age at DMEK (yrs)	Laterality	Indication for DMEK	Previous Ocular History	Redo DMEK	Type of DMEK Surgery
Patient #1	Female	76	Left	REPEAT DMEK	Cataract surgery with synechiolysis (2012)|irregular pupil|glaucomatous damage|previous DMEK graft early SGF (M10)|No diabetes	Yes	Graft exchange
Patient #2	Male	50	Left	PPBK	Complicated cataract surgery with posterior capsule tear and decentred MF-IOL|OHT | No diabetes	No	Standalone DMEK
Patient #3	Female	55	Right	FUCHS	Staged DMEK in fellow eye|No diabetes	No	Staged DMEK surgery
Patient #4	Female	58	Right	FUCHS	Amblyopic eye|myopic LASIK|No diabetes	No	Staged DMEK surgery

Patients	Type of Ocular Endotamponade	Rebubbling After DMEK	Total No. Bubbles in the AC	IOL Model	IOL Material	Time Between DMEK and IOLop Detection (wk)	Time to IOL Exchange (mo)
Patient #1	SF6 20%	No	2	AKREOS +23.50 D	26% WC hydrophilic acrylic	Onset 2 wk	12
Patient #2	SF6 20%	No	1	PHYSIOL MICRO F +21.50 D	25% WC hydrophilic acrylic	Onset 12 wk	11
Patient #3	SF6 20%	No	1	PRECIZON TORIC +30.25 SE (CYL 6.5)	Hybrid	Onset 44 wk	21
Patient #4	SF6 20%	No	1	PRECIZON MONOFOCAL +26.00 D	Hybrid	Onset 30 wk	24

LASIK, laser in situ keratomileusis; MF-IOL, multifocal intraocular lens; OHT, ocular hypertension; SGF, secondary graft failure; SF6, sulfur hexafluoride.

Cross-Sectional Study of Intraocular Lens Explantation

This study consisted of a cross-sectional analysis of all cases of IOL explantation because of post-DMEK IOLop with impact in vision that were observed between November 2021 and April 2022 at our institution and that had a minimum of 6 months of follow-up (F-U) after IOL explantation. The decision to explant an opacified IOL was made based on significant impact in vision, defined as loss of at least 1 line of Snellen best-corrected visual acuity (BCVA).

In patients fulfilling the inclusion criteria, electronic medical records (EMRs) were reviewed, and the following variables were collected for analysis: demographic data (age, sex), IOL model and material, indication for DMEK, ocular comorbidities, donor corneal endothelial cell density (ECD, cells/mm^2), need for rebubbling, time between DMEK surgery and IOLop, BCVA before DMEK, and BCVA before IOL explantation. Visual acuity was measured using a Snellen visual chart, and values were converted to logarithm of the minimum angle of resolution (logMAR) units for statistical analysis.

At the study visit, the following variables were collected and analyzed: BCVA ("final BCVA"), ECD and central corneal thickness (CCT) using specular microscopy, slit-lamp assessment of corneal transparency, and assessment of graft survival.

An exploratory analysis of all variables was performed. Continuous variables were described as mean (SD) or as median (IQR), depending on whether variables followed a normal distribution. To determine the statistical significance of the postoperative evolution in BCVA, one-way analysis of variance test was applied. Categorical variables were described as frequencies (%), and chi-square or Fisher exact test was applied to determine differences. The significance level α was 0.05. The statistical analysis was performed using *R Development Core Team* (2019) (R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria). The main outcome variable was the change in BCVA after IOL explantation compared with baseline BCVA before IOL explantation. Secondary outcomes were graft endothelial cell (EC) loss and graft survival at the study visit.

Historical Cohort Analysis of Intraocular Lens Opacification After DMEK

To determine risk factors for post-DMEK IOLop, we retrospectively reviewed the EMRs of 232 pseudophakic DMEK eyes performed between November 2011 and April 2022 (including standalone DMEK eyes and eyes that underwent either sequential or combined crystalline lens surgery and DMEK) retrieved from the institutional surgery database using the search terms "DMEK" or "EK." The variables collected included sex, age, indication for DMEK, patient diabetes *mellitus*, history of glaucoma, previous corneal grafts, axial length, history of high myopia, anterior chamber depth, IOL material and WC, and need for rebubbling after DMEK. Regression analysis was performed. Univariate logistic regression was performed to determine factors associated with IOLop. The covariables that reached a *P*-value <0.20 in the univariate analysis were candidates for the logistic regression model.

TABLE 2. Visual Outcomes After Intraocular Lens Exchange in Eyes at the Study Visit

Patients	BCVA (LogMAR)				F-U After IOL Exchange (mo)	Residual Manifest Refraction at the Study Visit (D)
	Before DMEK	After DMEK, Before Significant IOLop	Before IOL Exchange	At Study Visit		
Patient #1	0.80	0.00	0.18	0.00	40	−0.75 -0.75 (150 degrees)
Patient #2	0.40	0.18	0.30	0.00	99	+1.00 –1.25 (105 degrees)
Patient #3	0.18	0.18	0.20	0.10	34	+2.25 –1.75 (140 degrees)
Patient #4	0.40	0.20	0.45	0.18	50	−0.25

Logistic regression model assumption, named logit linearity in logit, was verified by generalized additive models. To select the best multivariate models, we applied the Akaike Information Criterion (AIC), which balances the goodness of fit and the complexity of the model; the lower the AIC, the better the model. We compared different models with different combinations of predictors and chose the 1 with the lowest AIC value. The results of this model were expressed as estimates of the odds ratio and the corresponding 95% confidence interval (95% CI).

RESULTS

Cross-Sectional Study: Outcomes of IOL Explantation

During the recruitment period, 117 DMEK eyes of 77 patients attended the visits at our center. Of those, 10 eyes had IOLop, of which 6 eyes were paracentral or small focal opacities of the anterior surface of the IOL not affecting BCVA, and 4 eyes of 4 patients matched the study inclusion criteria. The baseline data of these cases are presented in Table 1. Patient's age at DMEK surgery ranged between 50 and 76 years. Three eyes had some ocular comorbid condition: patient #1 had history of complex cataract surgery with irregular pupil and glaucoma and underwent repeat DMEK because of early secondary graft failure; patient #2 had a history of complicated cataract surgery with a decentered IOL and ocular hypertension (OHT); and patient #4 had history of myopic laser in situ keratomileusis ablation. In all cases, the ocular endotamponade gas used was sulfur hexafluoride 20% (SF6). One eye (patient #1) had history of a previous DMEK graft, whereas the remainder had no previous corneal grafts. Because no eyes had required rebubbling after DMEK, the total number of gas bubbles in the anterior chamber (AC) was 2 in patient #1 and 1 in the remainder (patients #2, #3, and #4). Two eyes had hydrophilic acrylic IOLs with 25% to 26% WC [patient #1 Akreos IOL (Bausch and Lomb); patient #2 Physiol Micro F (PhysIOL)], and the other 2 eyes (patients #3 and #4) had hybrid hydrophobic and hydrophilic monomers, the precise WC of which are not reported by the company (Precizon Monofocal, Ophtec). Time between DMEK and detection of IOLop ranged from 2 to 44 weeks, and time between DMEK and IOL explantation because of significant impact in visual acuity ranged from 11 to 24 months.

Surgery was performed under local anesthesia and sedation in all cases. All eyes underwent IOL exchange safely. Opacified IOLs were cut and explanted via a 2.75-mm incision. Three eyes (patients #1, #2, and #3) required anterior vitrectomy (patient #2 had a posterior capsule rupture during his cataract surgery at another institution; patients #1 and #3 had a previous Nd: YAG laser capsulotomy). Two of these cases had inadequate support for implantation of sulcus IOL, and in these cases, the incision was sutured, and a standard 5.2-mm posterior limbal biplanar incision was made for implantation of an iris-claw IOL (Artisan Aphakia, Ophtec). The third case had a 3-piece IOL implanted in the ciliary sulcus (Acrysof MA50BM, Alcon Laboratories, Inc). Patient #4 had a single-piece IOL (enVista, Bausch & Lomb Surgical) implanted in the capsular bag.

Visual outcomes of these cases are presented in Table 2. BCVA before last DMEK surgery ranged between 0.18 and 0.80 logMAR. In all cases, a decline of at least 1 line of BCVA was observed because of postoperative IOLop, with a median BCVA at the time of IOL explantation of 0.25 (0.19–0.41) logMAR. After IOL exchange, visual recovery was observed between postoperative day 1 and 60; 1 eye had a delayed visual recovery because of postoperative CME. At the study visit, median F-U after IOL exchange was 45 (35.5–86.8) months (range: 34–99 months). At the study visit, median BCVA was 0 (0.00–0.10 logMAR), which was clinically and statistically significant compared with BCVA before IOL exchange ($P = 0.041$).

After IOL explantation, 2 eyes had OHT requiring hypotensive drops, and 1 had postoperative CME, which resolved after treatment. At the study visit, all eyes had clear corneas with functioning DMEK grafts. On specular microscopy performed at the study visit (Fig. 1), CCT ranged between 462 and 543 μm (in comparison with the CCT before DMEK surgery ranging between 599 and 665 μm), and ECC ranged between 397 and 1143 cells/mm^2, corresponding to an EC loss of 57.7% to 85.3% (donor graft ECD ranged from 2400 to 2700 cells/mm^2).

Historical Cohort—Risk Factors for IOL Opacification After DMEK

In the historic cohort of 232 pseudophakic DMEK eyes, IOLop at postoperative F-U slit-lamp examination was documented in 21 eyes (9.05%). Five eyes (23.8%) had

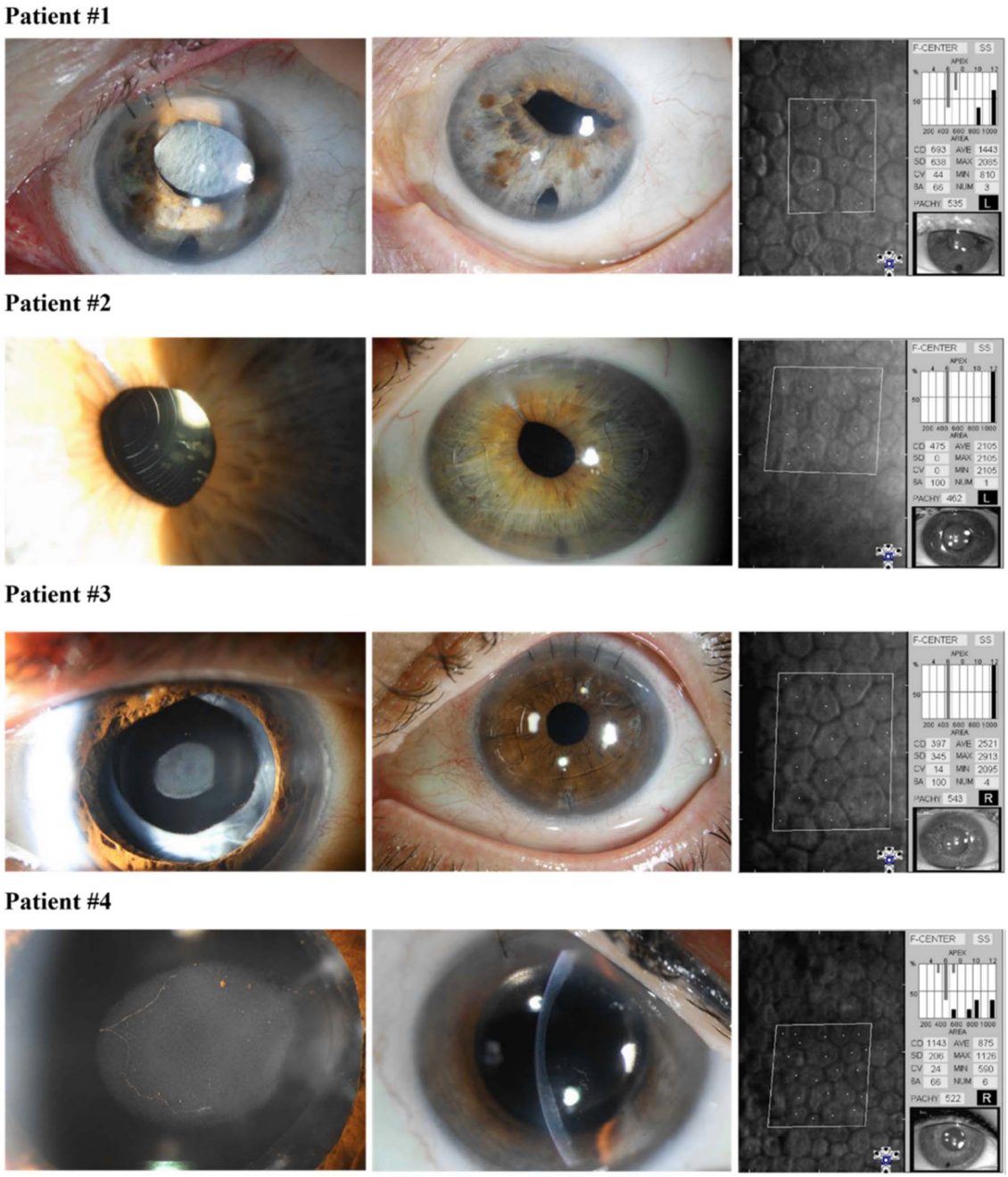

FIGURE 1. Anterior segment photographs of opacified IOL after DMEK (left), and during postoperative follow-up after IOL exchange retrieved from the patients' EMRs (middle). Specular microscopy measurements of postoperative EC count and pachymetry of the patients performed at the study visit. (The full color version of this figure is available at www.corneajrnl.com.)

history of previous EK grafts, 3 of which had 2 or more previous grafts. Six eyes (28.6%) had required rebubbling of the last DMEK graft; the mean number of rebubblings was 1.76 ± 1.09 (range = 1–5). In 13 of these eyes, information on the IOL model was available, with 2 of the cases occurring with hydrophobic IOL models (15.4%), and the remainder (84.6%) with hydrophilic acrylic or "hybrid" IOL models (hydrophobic plus hydrophilic monomers).

In these 21 eyes, median BCVA before detection of IOLop was 0.10 (0.04–0.20) logMAR (range: 0–0.40 logMAR), 0.19 (0.09–0.33) logMAR after detection of IOLop (range: 0–0.45 logMAR), and at last F-U observation (median F-U = 48 (24–60) months was 0.10 (0.04–0.23) logMAR (range: 0.10–0.40 logMAR). After excluding the cases of IOL exchange (n = 13), median BCVA was 0.10 (0.04–0.20) logMAR after DMEK and was unchanged after detection of IOLop.

This historical cohort included the 4 cases that were observed in clinic in the cross-sectional study and identified 4 more cases of IOL exchange: 1 eye underwent IOL exchange with a functional graft at last F-U 9.5 years after DMEK; another case underwent PKP (glaucoma tube-related corneal decompensation) with IOL exchange; the third eye was an eye where 2 DMEK grafts were performed to rescue a failed PKP graft, where PKP was later performed and only later IOL exchange was performed; and the other case was a case of 2 DMEK grafts performed to rescue a PKP graft, after the first DMEK graft the sulcus toric IOL opacified and was explanted, and after the second DMEK graft the in-the-bag IOL opacified, and PKP was performed combined with IOL exchange because the second DMEK graft had failed. In these 8 cases, median BCVA dropped from 0.18 (0.14–0.20) logMAR to 0.30 (0.20–0.40) logMAR upon detection of IOLop, corresponding to a decrease in approximately 2 Snellen lines of BCVA, and after IOL exchange final BCVA was 0.10 (0.05–0.14) logMAR.

In this cohort, 105 eyes had information on IOL material, and logistic regression analysis was performed to analyze risk factors for IOLop (n = 105). Variables that showed a *P*-value <0.20 in the univariant analysis (see Supplemental Table 1, Supplemental Digital Content 1, http://links.lww.com/ICO/B691) were candidates for the multivariate analysis and included indication for DMEK, IOL material, rebubbling, F-U time, axial length ≥23.27 mm, and anterior chamber depth ≥3.36 mm. The final multivariate logistic regression model retained the variables "IOL material" and "number of rebubblings" as independent variables predictive of post-DMEK IOLop (Table 3). There was a very strong association between IOL models with high WC and IOLop ($P = 0.0005$) and each rebubbling was strongly associated with a 9.5-fold increase in the likelihood of post-DMEK IOLop ($P = 0.0138$). There was a nonstatistically significant trend toward a higher likelihood of IOLop in eyes that underwent EK regrafting ($P = 0.0805$).

TABLE 3. Multivariate Logistic Regression Model Predictive of the Risk of Intraocular Lens Opacification After DMEK

Variable (N = 105)		OR	95% CI Inf	95% CI Sup	*P*
IOL material	Nonhydrophobic versus hydrophobic	65.5	9.4211	1302.034	0.0005*
No. of rebubblings		9.51	1.7807	77.8558	0.0138*
Indication for DMEK	Regraft versus other	5.47	0.8528	46.4731	0.0805

OR, odds ratio; 95% CI, 95% confidence interval.
*P value < 0.05.

DISCUSSION

Intraocular lens opacification is an infrequent but likely underreported complication after DMEK. Based on our historic cohort analysis, we have estimated a 9.05% rate of IOLop, which is within the reported range derived from the limited literature available, where there is a widely variable incidence ranging between 0.44% and 12.9%.[2–4] The incidence and severity of opacification and the time to opacification would be expected to vary depending upon the IOL models used in different studies. Our relatively high incidence of IOLop may also be related to the high number of "hybrid" IOLs that were implanted before 2015. Because we observed the first few cases of IOLop, we have abandoned IOLs with high WC in those eyes where the corneal endothelium may be at risk at the time of cataract surgery and in those cases where DMEK is planned (either as staged surgery or as triple DMEK).

The time between DMEK and the recognition of IOLop is highly variable, varying from few weeks to years after DMEK.[3,4] In our study, IOLop onset was detected as early as 2 weeks postoperatively and up to 10 months (44 weeks) after DMEK surgery.

Interestingly, our cross-sectional analysis suggests that IOL opacification tends to worsen once the process has started; this is the reason why although the onset of IOLop ranged from 2 weeks to 44 weeks, IOL exchange was only performed 11 to 24 months after DMEK. We have observed in our retrospective cohort that IOL materials with higher WC and higher number of rebubblings were strong, independent risk factors for post-DMEK IOLop, and a nonstatistically significant trend toward postoperative IOLop in EK regraft eyes. In our retrospective cohort, 84.6% of cases were "hybrid" or hydrophilic acrylic IOLs. Besides, in our cross-sectional study of eyes that underwent opacified IOL exchange, all eyes had hydrophilic acrylic or an "hybrid" IOL materials. Although IOL materials with high WC is likely the single most important independent risk factor for post-DMEK IOLop,[3,4] as is the case after Descemet stripping (automated) endothelial keratoplasty (DSEK/DSAEK),[7–9] we have observed opacifications in eyes with hydrophobic IOLs as well, as have other authors.[3,4] The increased risk of post-EK IOLop in eyes needing rebubbling and regraft eyes likely reflects the "total" exposure of the IOLs to the endotamponade gas bubbles in the AC.[3,7] Schrittenlocher et al have also observed that patients with post-DMEK IOLop had higher rebubbling rates than patients without,[3] but Lorenzana-Blanco et al[4] did not observe an association between rebubbling and post-DMEK IOLop in their study. Other risk factors for post-EK IOLop (both DSEK/DSAEK and DMEK) have been proposed inconsistently, including diabetes *mellitus*, glaucoma, and deep AC.[7] There is controversy as to whether the type of gas used for tamponade used for appositioning the DMEK graft against the recipient's posterior stroma influences risk of postoperative IOLop. Our standard gas for tamponade of the DMEK graft is SF6 20%, and the same applies in cases where rebubbling is performed. In the study by Schrittenlocher et al,[3] 86% of cases of IOLop occurred in eyes where room air was used for tamponade, but no associations were found between type of gas and IOLop in the study by Lorenzana-Blanco et al.[4]

Importantly, although many of the cases of IOL opacifications after DMEK are not visually significant either for their density of for their paracentral location,[9] our findings suggest that a relatively high proportion of cases may have

a significant impact in BCVA and require explantation. Based on our historical cohort analysis, up to one-third of cases of post-DMEK IOLop may affect BCVA over 1 Snellen line and require explantation, but we highlight that in some of these cases, vision was also significantly affected by DMEK graft failure requiring a new corneal graft. Our estimate is in line with a recent report,[4] but it is higher from another study where the authors only explanted one of 14 opacified IOLs.[3] However, we consider that these are rough estimates, because it is possible that in some cases (in all studies), the IOL was not explanted despite BCVA decline; some studies have found a trend toward worse BCVA in affected eyes compared with unaffected DMEK eyes, even though IOL explantation was only considered in 7% to 20% of cases.[3,4] The decision of explanting an opacified IOL in this setting must carefully balance the degree of visual loss with the potential surgical complications that may lead to worse visual outcomes and/or pose risks for the DMEK graft.

To the best of our knowledge, ours is the first study to date to include detailed outcomes (both functional and anatomical, including EC loss and corneal thickness data) and safety of IOL exchange in the setting of post-DMEK IOLop, with a long F-U time after IOL exchange of nearly 4 years to support the relevance of our findings. It also reinforces the findings from the previous studies that are remarkably limited.[3,4] In our study, IOL exchange was feasible and relatively safe in all 4 eyes. After IOL exchange, we observed a quick visual recovery and a clinically significant improvement in final BCVA. This is in line with a recent study, where visual acuity improved from 1.75 to 0.60 logMAR after IOL exchange in DMEK eyes with opacified IOLs.[4] However, we highlight that IOL exchange is challenging in these cases, especially if patients have previous posterior capsulotomy. Perioperative complications include posterior capsular rupture and vitreous loss requiring anterior vitrectomy, zonular damage, postoperative CME, corneal decompensation, OHT and glaucoma, uveitis, and suprachoroidal hemorrhage.[10–12] Although in our study all cases had clear corneas with functioning DMEK grafts at the study visit, these eyes may have accelerated EC loss (which can be due to iatrogenic trauma and due to perioperative inflammation or IOP increases), and this may pose the DMEK graft at risk for late endothelial graft failure in the medium term. Intraocular lens explantation has resulted in DMEK graft failure in anecdotal reports.[2] The main limitation of our study is the small sample size of eyes that underwent IOL exchange. In addition, there was a high percentage of cases in the historical cohort where no information on the IOL model and material was available. This is because our institution has a broad, international referral basis for DMEK, and so data on cataract surgeries and type of IOLs performed elsewhere was not available on the institutional EMRs in most cases. We note that the proportion of missing data on IOL type and material is in line with those of previous studies of post-DMEK IOLop. In the large retrospective studies by Lorenzana-Blanco et al and Schrittenlocher et al, missing data on IOL type and material occurred in 40% and 52% of cases, respectively.[3,4]

In conclusions, IOL opacification after DMEK surgery is a relatively infrequent complication, but up to one-third of eyes may require IOL exchange or explantation because of significant impact in vision. Main risk factors for post-DMEK IOLop are IOL materials with high WC and rebubbling. Intraocular lens exchange is feasible, safe and effective in restoring good visual function. Although we observed no cases of graft failure in our study, these eyes may have an accelerated rate of EC loss, which may place the graft at risk for late endothelial graft failure.

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